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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/885,468   | 06/19/2001  | Richard S. Stack     | ACS-57785           | 6866             |
| 24201  | 7590        | 12/11/2003           | EXAMINER            |                  |
| FULWIDER PATTON LEE & UTECHT, LLP<br>HOWARD HUGHES CENTER<br>6060 CENTER DRIVE<br>TENTH FLOOR<br>LOS ANGELES, CA 90045 |             |                      | DAVIS, DANIEL J     |                  |
|  |             | ART UNIT             |                     | PAPER NUMBER     |
|  |             | 3731                 |                     |                  |
| DATE MAILED: 12/11/2003<br>6   |             |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 09/885,468             | STACK ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | D. Jacob Davis         | 3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 26 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 29-34, 36-45, 47-53 and 56-60 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 57 is/are allowed.
- 6) Claim(s) 29-34, 56, 58 and 59 is/are rejected.
- 7) Claim(s) 36-45, 47-53 and 60 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 June 2003 is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____.                                   |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 30, 56, 58 and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by Mackenzie (US 6,019,777). Mackenzie discloses a method for entrapping plaque particles against a vascular wall (Figs. 7-10). He discloses a tubular sheath 34 (the distal portion of what Mackenzie describes as a sheath), a deployment catheter 28 (what is referred to by Mackenzie as the sheath), and a tubular member 15,22. As illustrated in Fig. 10, the tubular sheath 34 is distinct from, but unitary with the deployment catheter 28. Inherently, the tubular sheath 34 is attached to the catheter 28. The sheath is expanded such that a delivery catheter could partially deploy and expand an implantable medical device. The stent is expanded such that a balloon having a stent could be held within the sheath, pass through the sheath, and then deploy and expand the stent. The sheath is expanded by a balloon catheter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 that form the basis for the rejections under this section made in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
- (c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mackenzie in view of Walker (US 5,320,604). Mackenzie fails to disclose the use of perforations on the deployment catheter. Nevertheless, Walker discloses a balloon catheter (Fig. 1) having perforations 54 on the catheter to deliver a "plaque solubilizing liquid" (Col. 1, lines 24-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Mackenzie deployment catheter as taught by Walker to add perforations to deliver a "plaque solubilizing liquid."

Claims 32-34 are rejected under 35 U.S.C. 103(c) as unpatentable over Mackenzie in view of Wijay (US 5,643,278). Mackenzie is silent regarding the sheath material. Nevertheless, Wijay discloses a balloon catheter having a polymer sheath (Col. 4, lines, 1-5), which is strong, flexible, and biocompatible. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

make the Mackenzie sheath out of polymer as taught by Wijay because polymers are strong, flexible, and biocompatible.

Wijay is silent regarding the yield strength or the tensile strength. Nevertheless, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the sheath having a yield strength of between 50 and 300 psi and a tensile strength of over 2000 psi in order to withstand the pressures and stresses associated with radial expansion (Fig. 10) and advancement through the tortuous path.

#### ***Allowable Subject Matter***

Claim 57 is allowed.

Claims 36-45, 47-53, and 60 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed September 26, 2003 have been fully considered but they are not persuasive. The distal end of the sheath may broadly be interpreted as a "section," to use another term. "End" is not limited to the most distal point.

As described in the rejection of the claims, Mackenzie does disclose the use of a "radially, outward, deformable tubular member," which comprises the balloon 22.

***Conclusion***

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 3731

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD  
December 3, 2003



MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700